

Application No. 09/710,181
Amendment "H" dated December 14, 2004
Reply to Office Action mailed August 25, 2004

REMARKS/ARGUMENTS

Claims 41-42 and 44-90 are pending, wherein claims 41, 59, 65, 72, 77, 81 and 86 have been amended. Claim 43 has been cancelled, and new claims 87-90 were added.

Applicants amended the continuing data at the beginning of the application in order to restore it to how it was when the application was originally filed (*i.e.*, the above-identified application, when originally filed, claimed priority to U.S. application Serial No. 09/190,709, filed November 12, 1988, which is the parent of U.S. application Serial No. 09/694,516, filed October 23, 2000). Applicants also updated the continuing data to note that the '516 application issued as U.S. Patent No. 6,368,576. The present application now has an effective filing date of November 12, 1998.¹

Applicants incorporate by reference any arguments made in the previous amendments to the extent they still apply to the claims as now amended. For example, Applicants still maintain that the comparative study is strong evidence that the claims are unobviousness over the claims of the applied art.

I. REJECTION OF CLAIMS UNDER 35 U.S.C. § 102(b)

The Office Action rejects claims 41, 42 and 46-86 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,851,512 ("'512 patent"). The '512 patent discloses two ranges for the tooth desensitizing agent (one example of which is potassium nitrate): (1) "about 0.1% to about 10%", the preferred range, and (2) "about 1% to about 7%", the more preferred range. Col. 8, lines 57-60. The claims in the present application claim three different ranges or amounts: (1) "about 0.01% to about 2%", the preferred range; (2) "about 0.05% to about 1%"; and (3) "about 0.5%". According to MPEP § 2131.03:

When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, the reference teaches a broad range, and

¹ The four-month claim to priority rule in 35 U.S.C. § 120 is not applicable here because the present application was filed before November 29, 2000 and/or because a claim of priority to the '709 application was, in fact, made within four months of filing the current application (*i.e.*, it was made at the time of filing).

Application No. 09/710,181
Amendment "I1" dated December 14, 2004
Reply to Office Action mailed August 25, 2004

there is evidence of unexpected results within the claimed narrow range, ... it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims.

(Emphasis added.)

The underlined portion of MPEP § 2131.03 directly applies here. The claims of the present application claim three narrow ranges, the '512 patent discloses two broad ranges, and Applicants have presented evidence of unexpected results within the claimed narrow ranges. The broadest claimed range at issue in the present application (about 0.01-2%) overlaps less than 20% of the first range disclosed in the '512 patent (*i.e.*, 0.1-2% of 0.1-10%) and only one-seventh (or 14.3%) of the second disclosed range (*i.e.*, 1-2% of 1-7%). That means that more than 80% of the preferred range disclosed in the '512 patent and six-sevenths (or 85.7%) of the more preferred range are outside the broadest range of the present application. The narrower claimed ranges (*i.e.*, about 0.05-1% and about 0.5%) cover even less of the preferred '512 patent range, and they either only touch or actually fall outside the more preferred range in the '512 patent.

In view of the very small degree of overlap between the narrow ranges claimed in the present application compared to the broad ranges in the '512 application, Applicants submit that the claimed ranges at issue are not disclosed with "sufficient specificity to constitute an anticipation". See MPEP § 2131.03. Moreover, the results of the comparative study are "evidence of unexpected results within the claimed narrow range". *Id.* (emphasis added).

MPEP § 2131.03 goes on to state the following:

The unexpected results may also render the claims unobvious. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See MPEP § 2131.02. A 35 U.S.C. 102/103 combination rejection is permitted if it is unclear if the reference teaches the range with "sufficient specificity." The examiner must, in this case, provide reasons for anticipation as well as a motivational statement regarding obviousness.

In response to Applicants' proffer of evidence regarding the surprising and expected results of using a reduced quantity of potassium nitrate within the narrow claimed ranges, the PTO states that "the claims are far broader than the unexpected results provided by the Applicant." However, the MPEP and case law provide the following rule:

Application No. 09/710,181
Amendment "I" dated December 14, 2004
Reply to Office Action mailed August 25, 2004

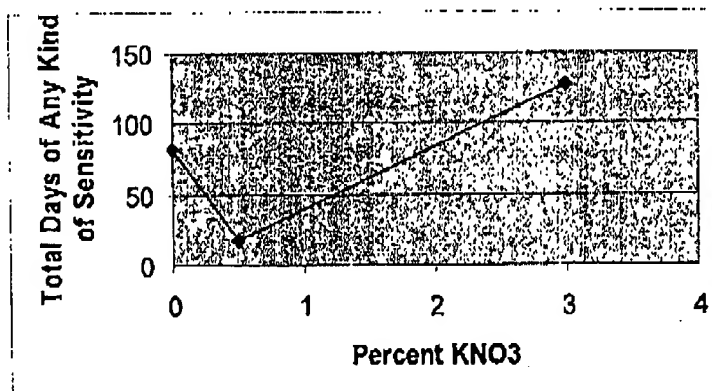
[T]he unobviousness of a broader claimed range, can in certain instances, be proven by a narrower range of data. Often, one having ordinary skill in the art may be able to ascertain a trend in the exemplified data which would allow him to reasonably extend the probative value thereof. . . .

In re Kollman, 595 F.2d 48, 56 (CCPA 1979). The MPEP recognizes this reading of *Kollman*:

The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof.

MPEP § 716.02(d) (citing *Kollman*).

Here, there are essentially three data points (0%, 0.5%, 3%), one of which is within the claimed ranges (about 0.01%-2%, about 0.05%-1%, about 0.5%) and two of which are outside. However, one of ordinary skill in the art can definitely "ascertain a trend in the exemplified data which would allow him to reasonably extend the probative value thereof." *Kollman*, 595 F.2d at 56. The chart below shows the trend:



There are several "trends" that can be discerned from this data. First, sensitivity *increases* from 0.5% potassium nitrate to 3% potassium nitrate. Second, sensitivity at 0% potassium nitrate is *lower than* sensitivity at 3% potassium nitrate. Both of these are

Application No. 09/710,181
Amendment "11" dated December 14, 2004
Reply to Office Action mailed August 25, 2004

"unexpected results." Third, sensitivity decreases from 0% potassium nitrate to 0.5% potassium nitrate. This is not an "unexpected result."

The "probative value" of the data can be "reasonably extend[cd]" to observe that including 2% potassium nitrate within a dental bleaching composition would be reasonably expected to provide about the same level of sensitivity as no potassium nitrate at all. Therefore, the data also reasonably implies that some range of potassium nitrate more than 0% and less than about 2% will decrease sensitivity compared to including either no potassium nitrate or 3% potassium nitrate. That is an unexpected result because it would be expected that 3% potassium nitrate should *decrease* sensitivity compared to values between 0% and 2% (*i.e.*, including more desensitizing agent should desensitize more, not less, than including about 0.01% to about 2% of the same component). In fact, the comparative study and trends reasonably deduced from the study show the counterintuitive result that including 3% potassium nitrate was worse in desensitizing teeth than including less or even no potassium nitrate. That is clearly unexpected. The foregoing analysis demonstrates that, at the very least, the data and "reasonable exten[sions]" thereof show unexpected results for the entirety of the claimed ranges. On this basis alone, Applicants submit that the claims are neither anticipated by, nor obvious over, the '512 patent.

A. Effect of Earlier Filing Date

As noted above, the above-identified application has been amended so that it now has an effective filing date of November 12, 1998. The effect of this is that it removes the '512 patent as prior art. That is because the present application and the '512 patent name the same inventive entity (*i.e.*, the '512 patent names Dan E. Fischer as sole inventor and also includes a Certificate of Correction adding Steven D. Jensen as a co-inventor by granted petition). Because the present application has an effective filing date that pre-dates the issue date of the '512 patent, and because the '512 patent and the present application have the same inventive entity, the '512 patent is not prior art under 35 U.S.C. § 102(c).

B. Effect of Incorporating Claim 43 into Independent Claims

Independent claim 41 was amended to incorporate the limitation of cancelled claim 43. Independent claims 59, 65, 72, 77, 81, and 86 were likewise amended. Applicants note that

Application No. 09/710,181
Amendment "11" dated December 14, 2004
Reply in Office Action mailed August 23, 2004

dependent claim 43 does not currently stand rejected as being anticipated by any reference under 35 U.S.C. § 102, or obvious under any reference under 35 U.S.C. § 103. For this additional reason, Applicants submit that the claims as amended are neither anticipated by nor obvious over the prior art of record.

II. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION OF CLAIMS 43-45 OVER THE '512 PATENT

The Office Action rejects claims 43-45 under the judicially-created doctrine of obviousness-type double patenting as being obvious over claims of the '512 patent in view of the disclosure of U.S. Patent No. 5,985,249 ("249 patent"). In response, Applicants reincorporate their arguments set forth above relative to the comparative study. According to MPEP § 804:

A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In Re Braithwaite* F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination. *In Re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1999); *In Re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

MPEP § 804 goes on to state that the factual inquiry set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that is applied for determining obviousness under 35 U.S.C. § 103 is employed when making an obviousness-type double patenting analysis. One of the factors includes "evaluat[ing] any objective indicia of nonobviousness". The comparative study is objective evidence that the claims are unobvious over the claims of the '512 patent according to MPEP § 804. On this basis alone, Applicants submit that the claims as now amended are not obvious over the '512 patent.

Moreover, Applicants note that the '249 patent is no longer citable as prior art under 35 U.S.C. § 102(a) since it issued after the effective filing date of the present application (*i.e.*, the '249 patent issued November 16, 1999, while the present application now has an effective filing date of November 12, 1998). As a result, the '249 patent is only citable as prior art, if at all,

Application No. 09/710,181
Amendment "II" dated December 14, 2004
Reply to Office Action mailed August 25, 2004

under 35 U.S.C. § 102(e)². However, under the provisions of 35 U.S.C. § 103(c), art that is only citable under 35 U.S.C. § 102(e) may not be used to establish the obviousness of a claim. As a result, the claims as now amended are nonobvious over the claims of the '512 patent, since the '512 patent may not be combined with the '249 patent to establish obviousness.

III. OTHER OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

The Office Action rejects claims 72-85 under the judicially-created doctrine of obviousness-type double patenting as being obvious over the claims of U.S. Patent No. 6,306,370 ("370 patent"). Applicants note that none of the other independent claims were deemed to be obvious over the claims of the '370 patent. After reviewing the differences between independent claims 72, 77, 81 and the other independent claims, Applicants determined that the only substantive difference, other than being composition rather than method claims, was that claims 72, 77 and 81 omitted the phrase "so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth". Because this phrase has now been added to each of independent claims 72, 77 and 81, Applicants submit that claims 72-85 are no longer obvious over the '370 patent for the same reason why, *e.g.*, independent claim 41 was not deemed to be obvious over the '370 patent. Reconsideration and withdrawal of this rejection is respectfully requested.

The Office Action rejects claims 41, 42, 46-55, 58-69, and 72-85 under the judicially-created doctrine of obviousness-type double patenting as being obvious over the claims of U.S. Patent No. 6,309,625 ("625 patent"). Applicants note that dependent claim 43 was not rejected over the '625 patent claims. Because the limitation of claim 43 has now been incorporated into each of the independent claims, Applicants submit that the claims as now amended are not obvious over the claims of the '625 patent.

² Applicants do not admit that the '249 patent is, in fact, prior art since the sole named inventor is a co-inventor of the subject matter claimed in the present application. Applicants reserve the right to file an affidavit or declaration under MPEP § 706.02(k) stating that any "unclaimed invention disclosed in the copending application [that issued as the '249 patent] was derived from the inventor of the [present] application and is thus not invention 'by another'".

Application No. 09/710,181
Amendment "H" dated December 14, 2004
Reply to Office Action mailed August 25, 2004

IV. NEW CLAIMS 87-90

New dependent claim 87 was added to recite a Markush group of preferred tackifying agents used in combination with the solvent recited in claim 86. Applicants also point out that none of the claims of the '512 patent recite "a solvent together with a tackifying agent" as now recited in claim 86. For this additional reason, Applicants submit that claims 86 and 87 are not obvious over the claims of the '512 patent.

New independent claim 88 recites a method of manufacturing a dental bleaching composition. Dependent claim 89 recites specific tackifying agents, while dependent claim 90 recites a dental bleaching composition in "product-by-process" format (i.e., a composition formed according to the method of claim 88).

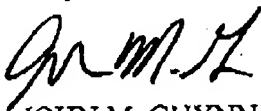
In the event the Examiner believes that claims 88-90 define patently distinct subject matter, the Examiner is invited to initiate a telephonic interview with the undersigned attorney in order to request an election of claims in the event claims.

V. CONCLUSION

Applicants believe that the claims as now presented are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 15th day of December 2004.

Respectfully submitted,



JOHN M. GYNN
Registration No. 36,153
Attorney for Applicant
Customer No. 022913

JMG:mla
KCS0000003330V001